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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,445	06/21/2001	Robert H. Frater	P 279185 P95US1	2733

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EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 03/17/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,445	FRATER ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-33 and 125-135* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-33 and 125-135* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *19*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated December 23, 2003. Claims 23-33 and 125-135 are pending.

Response to Arguments

1. Applicant's arguments filed December 23, 2003 have been fully considered but they are not persuasive.

Applicant's amendments and remarks have been carefully reviewed. However, as discussed in the interview dated December 10, 2003, applicant has failed to incorporated structural limitations to define over the prior art. On page 11 of the Remarks/Arguments section dated December 23, 2003, applicant states, "Applicants appreciated that the previous rejection of claims 23-33 has been withdrawn." However, the rejection has not been withdrawn and there was no agreement to withdraw the rejection.

Applicant discusses that Venegas is directed to an IPPB that delivers intermittently. Applicant states, "To maintain the seal, an elastic band, i.e., headgear, is used to hold the mask in place with a force sufficient to maintain the seal during inspiration." Venegas does not exert excessive, constant force, which would result in skin necrosis and/or sores. Venegas also recites, when the pressure in the mask of Venegas decreases, the constant force on the facial unit is decreased and the seal is eliminated, as discussed in the abstract. However, the seal in both the current application and that of Venegas is dependent on the pressure exerted by the straps,

and although the teaching of Venegas is for intermittent sealing the structure when the straps are tightened it is capable of providing a constant seal.

Applicant is reminded that in apparatus claims, the obligation is to consider the structural components. The structure of Venegas is capable of providing a continual seal, when the straps are tight. It appears that applicant is relying on functional limitations for patentability in an apparatus claim. The forces exerted by the straps, although not previously discussed, from a purely structural consideration could achieve applicant's claimed constant sealing given the straps have a direct impact on forces within the mask.

A close reading of applicant's specification would indicate to one with ordinary skill in the art that the force exerted by straps in applicant's disclosed invention could cause applicant's disclosed mask to operate in a range outside of that desired functional recitation. From a claim standpoint, it would appear the real difference might be how the straps are applied rather than structure. It appears applicant is trying to claim method terminology in an apparatus claim. Applicant's attention is drawn to the current application specification, where page 6 recites, "In one form, the predetermined force is a function of the displacement of the shell relative to the face. In another form, the predetermined force is a function of both mask pressure and displacement. In another form, the predetermined force is independently controlled..." In any case the straps and their tightness directly impact the forces on the face. The specification, on page 7, also discusses, that headgear coupled to a shell exerts forces on the shell and a face-contacting cushion, which transfers forces to the face. This allows for the tension in the

straps of the headgear to be generally less than a known mask to securely seal the mask, especially at mask air pressures below the maximum mask air pressure for therapy, providing greater patient comfort and compliance with the prescribed respiratory therapy regime. While some membrane-type cushion mask arrangements accommodate limited relative movement between the cushion and the wearer's face while maintaining a tolerable seal, the present invention increases accommodation without increasing strap pressure. This is clearly functional recitation and the claims have not provided any ***structural*** features of the bellows/gusset that accomplish this.

The rejection is reiterated below with additional comments. Further, the newly added claims are also addressed below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Regarding claim 132, the phrase "spring-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

4. Claim 132 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 132 includes the limitation "a pressure dependent and/or distant-dependant spring constant." The scope of this limitation is unclear. Any art rejection is as best understood.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 23-28, 125 and 126- 135 are rejected under 35 U.S.C. 102(b)/103(a) as being anticipated by Venegas in US Patent No. 5,047,297.

Venegas discloses a mask (10) for delivering breathable gas to a patient/user where the mask (10) has a shell (16) having a portion adapted to receive a supply of pressurized breathable gas and a user side, recited in column 1, lines 50-67; a cushion (12, 26) constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; headgear (22) constructed and arranged to attach the mask shell to the user, as stated in column 1, lines 50-67 and seen in figures 1 and 2; a gusset portion (14) having a first side attached to the user side of the shell, as seen in figure 1; and a mask that is a nasal mask, as seen in figure 1.

Regarding claims 23, 128, 129 and 135, the recitation a gusset portion that is constructed and arranged such that it can be selectively moved within a range of displacement to be set a distance between the mask shell and the cushion where, the gusset portion defines a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force F.sub.c of

the cushion on the user's face, wherein the mask shell, gusset portion, cushion and headgear are constructed and arranged with respect to one another in use so that the force Fc is maintained in approximately constant proportion to the pressure of the supply of pressurized breathable gas, and a total force and a total force of the mask on the face Fm is maintained within a range of about 35-108 grams per gf/cm.sup.2 pressure of the supply of pressurized breathable gas to thereby maintain the seal between the mask and the user's face over an operating pressure range of the mask, including a minimum pressure of the operating pressure range can be accomplished by Venegas and is dependent on how tightly the straps are tightened. Although Venegas teach to have the straps loose and the seal eliminated in portions of the breathing cycle, if the straps were tightened, the structure would be capable of performing the function recitation.

Regarding claims 24-26, the recitation, a force Fm that is maintained within a range of about 40-88 grams per gf/cm.sup.2 pressure of the supply of pressurized breathable gas and a force Fm that is maintained within a range of about 50-88 grams per gf/cm.sup.2 pressure of the supply of pressurized breathable gas; and an operating pressure range that is about 4-25 gf/cm.sup.2, are also dependent on the force of the straps on the mask and on the face and within the scope of the invention, given the structure the system.

Regarding claims 27 and 28, expansion and contraction of the gusset portion that permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of

the mask shell with respect to the user's face is also within the scope of the invention and again dependent on the tightness of the straps, as seen in figures 1-4 and Venegas also discloses a gusset portion (14) that includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas, as recited in columns 2-4 and seen in figures 1-4.

Regarding claim 127, the recitation, wherein, by selectively varying the length of the headgear straps upon initial set up of the mask system, the gusset portion is movable within a range of displacement to be set at a distance between the mask shell and the cushion, the gusset portion defining a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force Fc of the cushion on the users face, and wherein the mask shell, gusset portion, cushion and headgear are structured and arranged with respect to one another in use so that the force Fc is maintained to at least equal a minimum sealing force for the seal between the user and the mask at a minimum operating pressure of the mask, again can be accomplished by Venegas depending on how tightly the strap are tightened.

Regarding claims 130 and 131, the recitation, a gusset portion between the mask frame and the cushion, the gusset portion having a gusset area constructed and arranged such that at the operating pressure there is an

approximately linear relation ship between the force and the distance, where the structure is such that the force on the face increases as the frame is moved closer to the face, is also dependent on strap pressure.

Regarding claim 132, 133 and 134, the recitation, a gusset portion between the mask frame and the cushion where the gusset portion includes a sidewall having at least one of a pressure dependent projected area and a spring-like portion with a pressure-depended and/or distance-dependent spring constant such that the force and the distance are approximately inversely proportional at a given operating pressure in which the side wall includes both pressure-dependent projected area and the spring-like portion, is indefinite and the scope of the claim is unclear. Further, it would be dependent on strap pressure, which could be manually varied by Venegas.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 29-33, 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venegas in US Patent No. 5,074,297.

Venegas discloses that disclosed to claim 23. Although not explicitly recited, a gusset portion that includes a sidewall having a thickened cross-section at a base of the sidewall, where the thickened cross-section has a

generally uniform thickness; and a gusset portion that includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion are also within the scope of the invention, see column 3, lines 10-50. Therefore, it would be obvious to one with ordinary skill in the art to provide the gusset portion to have a sidewall having a thickened cross-section at a base of the sidewall, where the thickened cross-section has a generally uniform thickness; and a gusset portion that includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion for the purpose of a proper seal.

Further, element 16 of Venegas acts as a generally rigid backstop of the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion extends around substantially an entire periphery of the gusset portion. Additionally, it is within the scope of the invention to use the mask as a CPAP mask and when the straps are tightened could function as such.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

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